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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,413	02/08/2001	Bernard J. Banks	PC10901A	9774

7590

09/03/2003

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/779,413

Applicant(s)

BANKS ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

CLAIMS 1-11 ARE PRESENTED FOR EXAMINATION

Applicants' Request for Continued Examination and Amendment filed July 23, 2003 have been received and entered into the application. Accordingly, claims 1 and 10 have been amended.

Claim Rejection - 35 USC § 103

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al. (EP 0 882 719)[Harada et al. '719] and Harada et al. (WO 98/57938)[Harada et al. '938], each of record, for the reasons of record as set forth in the Office action dated January 21, 2003 at pages 2 and 3.

Applicants' amendment to claims 1 and 1-10 wherein the phrase "wherein the free blood plasma concentration after twenty four hours remains above the concentration providing efficacy for said endothelin-mediated disorder" has been inserted, as well as applicants' arguments at pages 6-7 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness for the following reasons.

Applicants have urged that a prima facie case of obviousness has not been made by the Examiner because the Examiner has not explained the specific understanding or principle within the knowledge of the skilled artisan that would have motivated one with no knowledge of Applicants' invention to select and use the compounds of the claims in the manner claimed. In response thereto, it is pointed out in Harada et al. '719 at page 14 line 6, that the compounds were administered to conscious rats. While in the case of the reference, such animals may not be considered "companion" animals, it would have nevertheless provided the skilled artisan with

Art Unit: 1614

the knowledge that such compounds could also be used in non-human animals, including those which are considered “companion animals”. The Examiner believes that such a teaching would have provided sufficient motivation to employ the compounds in not only rats, which some people do enjoy as “companion animals”, but to other such animals which may include not only those set forth in present claim 2, but which may also include other rodents such as mice or other animals such as ferrets, snakes, goldfish and llamas.

The Examiner will agree that, with respect to the two specific chemical compounds comparatively tested in dogs, it would not have been obvious to the skilled artisan that In a method of treating an endothelin-mediated disorder in a companion animal that is a dog, administration of any one of these two compounds in such dogs would result in having the free blood plasma concentration of these two compounds after twenty four hours remain above the concentration providing efficacy for said endothelin-mediated disorder. The Examiner, however, cannot agree with applicant's that the insertion of the phrase “wherein the free blood plasma concentration after twenty four hours remains above the concentration providing efficacy for said endothelin-mediated disorder” into the claims imparts patentable moment to the claimed subject matter because:

(A) In claims 10-11, such phrase does not impart any physical or otherwise material limitation to the claimed composition that is not found in the prior art compositions. It is not material in a composition/formulation-type claim as to how the composition/formulation is to be employed, but rather what such a composition/formulation is in a physical sense.

(B) The claims are not commensurate in scope with data upon which applicants' rely for their assertion of patentability. The showing with only 2 specific compounds in 1 type of

Art Unit: 1614

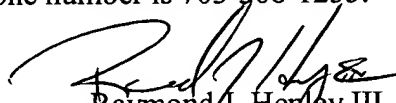
companion animal is insufficient to provide a reasonable basis to conclude that such results are representative of the results that could be achieved employing the genus of compounds presently claimed, especially because applicant's genus includes a compound shown not to meet the newly added claim recitation, i.e., the compound of Harada '938, Example 2, in all companion animals as presently claimed.

Accordingly, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 703-308-4652. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Raymond J. Henley III
Primary Examiner
Art Unit 1614

Henley; rjh
8/29/03